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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|------------------------------|----------------|----------------------|------------------------|------------------|--|
| 09/823,896 | 03/30/2001 | Marion R. Rice | 1011US07 | 7568 | |
| 75 | 590 05/10/2005 | | EXAM | INER | |
| CHRISTOPHER C. WINSLADE | | | NAJARIAN, LENA | | |
| 2135 N. CLIFT CHICAGO, IL | | | ART UNIT | PAPER NUMBER | |
| | | | 3626 | | |
| | | | DATE MAILED: 05/10/200 | 5 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | |
|---|---|---|---|---------------------|
| . Office Action Summary | | 09/823,896 | RICE ET AL. | |
| Office Action | Summary | Examiner | Art Unit | |
| | · · · · · · · · · · · · · · · · · · · | Lena Najarian | 3626 | |
| The MAILING DATE Period for Reply | of this communication app | ears on the cover s | heet with the correspondenc | e address |
| THE MAILING DATE OF - Extensions of time may be availab after SIX (6) MONTHS from the may - If the period for reply specified abo - If NO period for reply is specified a - Failure to reply within the set or ex | le under the provisions of 37 CFR 1.13 ailing date of this communication. we is less than thirty (30) days, a reply bove, the maximum statutory period w tended period for reply will, by statute, ter than three months after the mailing | 36(a). In no event, howeve within the statutory minimuliful apply and will expire SIX cause the application to be | r, may a reply be timely filed um of thirty (30) days will be considered (6) MONTHS from the mailing date of the come ABANDONED (35 U.S.C. § 133 | this communication. |
| Status | | | | |
| 1) Responsive to comr | nunication(s) filed on <u>30 M</u> | <u>arch 2001</u> . | | |
| 2a) This action is FINAL | 2b)⊠ This | action is non-final. | | |
| , — | n is in condition for allowar e with the practice under E | • | al matters, prosecution as to 35 C.D. 11, 453 O.G. 213. | the merits is |
| Disposition of Claims | | | | |
| 4)⊠ Claim(s) 1-30 is/are | pending in the application. | | | |
| • | im(s) is/are withdray | | on. | |
| 5) Claim(s) is/aı | re allowed. | | | |
| 6)⊠ Claim(s) <u>1-30</u> is/are | | | | |
| 7) Claim(s) is/a | | | | |
| 8) Claim(s) are | subject to restriction and/o | r election requireme | ent. | |
| Application Papers | | | · | |
| 9)⊠ The specification is o | bjected to by the Examine | r. | | |
| 10)⊠ The drawing(s) filed | on <u>30 March 2001</u> is/are: | a) accepted or b | objected to by the Exam | niner. |
| Applicant may not req | uest that any objection to the | drawing(s) be held in | abeyance. See 37 CFR 1.85(| a). |
| | | • | frawing(s) is objected to. See 3 | ` ' |
| 11) The oath or declarat | ion is objected to by the Ex | caminer. Note the a | ttached Office Action or form | n PTO-152. |
| Priority under 35 U.S.C. § 11 | 9 | | • | |
| a) ☐ All b) ☐ Some * | ·— | • | . , , , , , | |
| | es of the priority document | | | |
| <u> </u> | • | | ed in Application Noe been received in this Natio | |
| • | om the International Bureau | • | | mai Stage |
| • • | ailed Office action for a list | , | • | |
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| Attachment(s) | | | | |
| 1) Notice of References Cited (P) | ГО-892) | 4) 🔲 Int | erview Summary (PTO-413) | • |
| 2) Notice of Draftsperson's Paten | | 5) <u> </u> | per No(s)/Mail Date blice of Informal Patent Application her: | (PTO-152) |

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DETAILED ACTION

Drawings

- 1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: item 119 (page 7, line 17) and item 421 (page 12, line 14). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
- 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: item 149 (Fig. 1), item 345 (Fig. 3), and item 431 (Fig. 4). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each

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drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because its length exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 6. Claims 1-22 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:
 - (i) "the healthcare information": claim 1, lines 4-5

claim 5, lines 2-3

claim 12, lines 4-5

claim 16, lines 2-3

(ii) Claims 2-4, 6-11, 13-15, and 17-22 incorporate the deficiencies of claims 1,5, 12, and 16 and are also rejected.

Claim Rejections - 35 USC § 102

- 7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
 - A person shall be entitled to a patent unless -
 - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 1-7, 9-18, and 20-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Abreu (US 2001/0056359 A1).

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(A) Referring to claim 1, Abreu discloses an alerting healthcare network comprising (para. 2 of Abreu; the Examiner interprets "notification" to be a form of "alerting"):

healthcare alert information generated by a healthcare related agency (para. 12 of Abreu; the Examiner interprets "the FDA" to be a form of "healthcare related agency");

a patient database that stores patient information regarding a patient (para. 152, lines 17-22 of Abreu);

a first web server communicatively coupled to the patient database that evaluates the healthcare information and the patient information and generates at least one alert message based on the evaluation (para. 124, lines 21-27 and para. 140 of Abreu);

a healthcare provider computer, communicatively coupled to the web server, running browser software used by the healthcare provider to review the patient information (para. 132, lines 34-36 and para. 234, lines 17-33 of Abreu); and

at least one web page delivered by the web server to the healthcare provider computer that presents the at least one alert message for review by the healthcare provider (para. 12, lines 21-24 and para. 140 of Abreu).

- (B) Referring to claim 2, Abreu discloses wherein the healthcare related agency is the FDA (para. 12 of Abreu).
- (C) Referring to claim 3, Abreu discloses a second web server associated with the healthcare related agency, and wherein the first web server receives the healthcare alert information from the second web server (para. 123 of Abreu).

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(D) Referring to claim 4, Abreu discloses wherein the first web server periodically retrieves the healthcare alert information from the second web server (para. 26 of Abreu).

(E) Referring to claim 5, Abreu discloses wherein the second web server communicates the healthcare alert information to the first web server in real time when the healthcare information is generated (para. 185 of Abreu).

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- (F) Referring to claim 6, Abreu discloses wherein the alert message comprises a warning based on one or more of a current condition of the patient, a current medication of the patient, a diagnosis associated with the patient, current care being provided to the patient, and a medical history of the patient (see abstract of Abreu).
- (G) Referring to claim 7, Abreu discloses wherein the healthcare provider computer is one of a physician computer or a nurse computer (para. 137 of Abreu; the Examiner interprets "a hospital or doctor's office are notified" to be a form of "physician computer").
- (H) Referring to claim 9, Abreu discloses wherein the first web server is at a location remote from healthcare provider computer (para. 40, lines 1-16 of Abreu).
- (I) Referring to claim 10, Abreu discloses wherein the first web server is at a location remote from the second web server (para. 40, lines 1-16 of Abreu).
- (J) Referring to claim 11, Abreu discloses wherein the alert message is based on a suitability of the patient for participation in a clinical study (para. 12 of Abreu; the Examiner interprets "sample size" to be a form of "suitability" and "trial" to be a form of "clinical study").

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(K) Referring to claim 12, Abreu discloses an alerting healthcare network comprising (para. 2 of Abreu; the Examiner interprets "notification" to be a form of "alerting"):

healthcare alert information generated by a healthcare related agency (para. 12 of Abreu; the Examiner interprets "the FDA" to be a form of "healthcare related agency");

a patient database that stores patient information regarding a plurality of patients (para. 152, lines 17-22 of Abreu);

a first web server communicatively coupled to the patient database that evaluates the healthcare information and the patient information, and based on the evaluation, generates an alert message for each of selected ones of the plurality of patients (para. 124, lines 21-27 and para. 140 of Abreu; the Examiner interprets "usernames associated with the code" to be a form of "selected ones of the plurality of patients");

a plurality of healthcare provider computers, each corresponding to a respective one of the plurality of patients, communicatively coupled to the web server, and running browser software used by a healthcare provider to review patient information regarding the respective one of the plurality of patients (para. 132, lines 34-36 and para. 234, lines 17-33 of Abreu); and

the first web server delivering at least one web page to selected ones of the plurality of healthcare provider computers, each of the selected ones of the plurality of healthcare provider computers corresponding to a respective selected one of the

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plurality of patients, each at least one web page presenting the alert message for review by a healthcare provider (para. 12, lines 21-24 and para. 140 of Abreu).

- (L) Claims 13-16 repeat the same limitations of claims 2-5, and are therefore rejected for the same reasons given for those claims.
- (M) Referring to claim 17, Abreu discloses wherein each alert message comprises a warning based on or more of a current condition of the respective selected one of the plurality of patients, a current medication of the respective selected one of the plurality of patients, a current diagnosis for the respective selected one of the plurality of patients, current care being provided to the respective selected one of the plurality of patients, and a medical history of the respective selected one of the plurality of patients (see abstract of Abreu).
- (N) Referring to claim 18, Abreu discloses wherein each of the plurality of healthcare provider computers is one of a physician computer or a nurse computer (para. 137 of Abreu; the Examiner interprets "a hospital or doctor's office are notified" to be a form of "physician computer").
- (O) Referring to claim 20, Abreu discloses wherein the first web server is at a location remote from at least a portion of the plurality of healthcare provider computers (para. 40, lines 1-16 of Abreu).
- (P) Claim 21 repeats the same limitations of claim 10, and is therefore rejected for the same reasons given for that claim.
- (Q) Referring to claim 22, Abreu discloses wherein the alert message is based on a suitability of the respective selected one of the plurality of patients for participation in a

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clinical study (para. 12 of Abreu; the Examiner interprets "sample size" to be a form of "suitability" and "trial" to be a form of "clinical study").

(R) Referring to claim 23, Abreu discloses a method of providing an alert in an alerting healthcare system comprising:

retrieving patient information from a patient database regarding a patient (para. 283 of Abreu; the Examiner interprets "personal information database" to be a form of "patient database");

receiving healthcare alert information generated by a healthcare related agency (para. 12 of Abreu);

determining whether an alert is warranted for the patient based on the retrieved patient information and the healthcare alert information (para. 140 of Abreu; the Examiner interprets "usernames associated with the code for the harmful product" to be a form of "whether an alert is warranted for the patient");

communicating an alert message to a physician computer if it is determined that an alert is warranted for the patient (para. 137 of Abreu).

- (S) Referring to claim 24, Abreu discloses causing the alert message to be displayed on the physician computer (para. 137 of Abreu; the Examiner interprets "notification" to be a form of "alert message").
- (T) Referring to claim 25, Abreu discloses communicating, by the healthcare related agency, the healthcare alert information (para. 12 of Abreu).
- (U) Referring to claim 26, Abreu discloses wherein the healthcare alert information is retrieved from the healthcare related agency (para. 36 and para. 123 of Abreu).

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(V) Referring to claim 27, Abreu discloses a method of providing alerts in an alerting healthcare system comprising:

retrieving patient information from a patient database regarding each of a plurality of patients (para. 283 of Abreu; the Examiner interprets "personal information database" to be a form of "patient database");

receiving healthcare alert information generated by a healthcare related agency (para. 12 of Abreu);

determining whether an alert is warranted for the each of the plurality of patients based on the retrieved patient information and the healthcare alert information (para. 140 of Abreu; the Examiner interprets "usernames associated with the code for the harmful product" to be a form of "whether an alert is warranted");

communicating an alert message to a respective physician computer, for each of the plurality of patients for whom it is determined that an alert is warranted (para. 137 of Abreu).

- (W) Referring to claim 28, Abreu discloses causing the alert message to be displayed on each respective physician computer (para. 137 of Abreu; the Examiner interprets "notification" to be a form of "alert message").
- (X) Claims 29-30 repeat the same limitations of claims 25-26, and are therefore rejected for the same reasons given for those claims.

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2001/0056359 A1) in view of Kapp (US 2002/0010595 A1).
- (A) Referring to claim 8, Abreu does not disclose wherein the at least one web page presents a pop-up window for display of the at least one alert message.

Kapp discloses wherein the at least one web page presents a pop-up window for display of the at least one alert message (para. 53 and para. 6 of Kapp).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Kapp within Abreu. The motivation for doing so would have been to show indication of a problem (para. 6 of Kapp).

(B) Claim 19 repeats the same limitations of claim 8, and is therefore rejected for the same reasons given for that claim.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and apparatus for providing medication administration warnings (US 2001/0056358 A1) and research data collection and analysis (US 6,196,970 B1).

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Also included are provisional application 60/182,000, which is a priority document to applied reference, US 2001/0056359 A1 (Abreu) and provisional application 60/193,636, which is a priority document to applied reference, US 2002/0010595 A1 (Kapp).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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INSEPH THOMAS

SUPERVISORY PATENT EXAMINER
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Application/Control No. O9/823,896 RICE ET AL. Examiner Lena Najarian Applicant(s)/Patent Under Reexamination RICE ET AL. Page 1 of 1

U.S. PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|--|-----------------|--------------------|----------------|
| | Α | US-2001/0056359 A1 | 12-2001 | Abreu, Marcio Marc | 705/3 |
| | В | US-2002/0010595 A1 | 01-2002 | Kapp, Thomas L. | 705/2 |
| | С | US-6,196,970 B1 | 03-2001 | Brown, Stephen J. | 600/300 |
| | D | US-2001/0056358 A1 | 12-2001 | Dulong et al. | 705/2 |
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NON-PATENT DOCUMENTS

| * | • | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
| | U | US Provisional Application 60/193,636 |
| | V | US Provisional Application 60/182,000 |
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.